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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MATTHEWS, WILLIAM H	
ART UNIT	PAPER NUMBER
3774	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/673,528	WANG, LIXIAO	
	Examiner	Art Unit	
	William H. Matthews (Howie)	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 91-123* is/are pending in the application.

4a) Of the above claim(s) *102-104* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,91-101 and 105-123* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12-8-09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 7-14-09 contained duplicate references which were cited in the IDS of 5-15-09, thus the duplicate citations were lined through in the 7-14-09 IDS. Each of the references were considered, so it is unclear what Applicant is requesting on page 7 of Applicant's response. A reference need not be signed twice.

Response to Arguments

Applicant's arguments with respect to claims 1,91-101,105-123 have been considered but are not persuasive.

Initially, as to the interpretation of "drug", paragraph [0050] of Applicant's specification discloses the drug may be "to prevent restenosis or *for other treatment."* and *"All such materials* are referred to herein generally as "drugs"." Thus the specification does not limit the term "drug" to a medicine or pharmaceutical drug for treating restenosis. "Other treatment" may be considered an imaging treatment or the mere expansion of the stent whereby the gold coating assists the delivery and expansion of the stent.

With respect to Richter and claim 99, Examiner interprets mesh synonymus with "web" or interconnected segments having interstices therein. This is shown in Figure 3A, as noted in the previous office action.

With respect to Venbrux, for example, stent 12 may be considered to comprise first end portion 20 having a coating and ePTFE tube 16 sewn thereto, middle portion

18, and second end portion 17. Figure 1 clearly shows 17,18 are freee of coatings and ePTFE layer 16. Furthermore, the claims recite "end portions" whereby the portion may be considered the terminal end 17,18 or a region spaced from the terminal end such as the region denoted 20 in Figure 1.

With respect to Kranz, Examiner maintains the interpretation of "drug" as described above. **However,** the rejection of claim 108 has been withdrawn upon further review.

With respect to Scott, the amendment to require a coating *adhered* directly to the metal surface overcomes the rejection of claims 1 and 109, and their respective dependent claims. However, with respect to claim 108, the argument that a sleeve is not a coating is not persuasive. A coating is defined as a material covering a substrate, thus a sleeve meets the broadest reasonable interpretation of a coating as claimed. It is further noted that Scott makes a distinction between a sleeve and a coating that is dipped or covalently bound directly to the stent.

With respect to the 103 rejection over Berg in view of Scott, Nolting, and Jang, Applicant argues that Scott teaches away from coatings and thus any teachings flowing from Scott could not be combined with a coated stent such as Berg. This is not persuasive, as Scott teaches the concept of delivering drugs from a polymer substrate located all over a stent or only over a portion of a stent (i.e. a proximally located ring). In other words, Scott teaches the discovery that localized delivery of a drug requires less drug and imparts less systemic delivery of the drug. These teachings would have been clearly recognized as applicable to dip-coated or spray coated stents.

Furthermore, Scott teaches that prior coatings "cracked" upon expansion. The coating in Berg is improved and is flexible to expand with the stent, and is thus apparently different from the methods Scott might be considered to teach away from.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1,92-94,98-101 are rejected under 35 U.S.C. 102(e) as being anticipated by Richter USPN 6315794.

Richter disclose an expandable stent (fig 3A) comprising a coating of a drug on the stent ends wherein the middle is free of the drug. The coating 202 comprises a metallic material which is encompassed by the broadly claimed "drug", and in view of

the broad definition afforded the term in the specification at paragraph [0050] of the published application (note line 2 “or for other treatments” and the final line).

The stent may further comprise a second coating 102 which is the same or different as the first coating.

The outer ends are inherently more “loose” and flexible than the middle portion due to being unconnected at both sides.

Claims 1,91,95,100,101,108-110,114,119-120 are rejected under 35 U.S.C. 102(b) as being anticipated by Venbrux USPN 5,443,497.

Venbrux disclose in figure 1 an expandable stent (12 or 14) comprising an end portion having a coating thereon of adhesive or other polymer wherein the middle portion 16 is free of the coating. The coating may be sewn through to attach stent 16 such that apertures/perforations exist. See columns 2-3.

Claims 1,91-92,94,98-101 are rejected under 35 U.S.C. 102(e) as being anticipated by Kranz et al. USPN 6312456 (“Kranz”).

Kranz disclose an expandable stent (figure 2) comprising a coating of a drug on a stent end wherein the middle is free of the drug. The coating 4 comprises a metallic material which is encompassed by the broadly claimed “drug”, and in view of the broad definition afforded the term in the specification at paragraph [0050] of the published application (note line 2 “or for other treatments” and the final line).

The stent comprises a second different coating of silicone carbide.

The outer ends are inherently more “loose” and flexible than the middle portion due to being unconnected at both sides.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1,91,92,94,96-100,108-111,113,115-119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scott et al. USPN 5383928 ("Scott") in view of Myers et al. USPN 5700285 ("Myers").

Scott disclose a balloon expandable metal stent comprising a sleeve coating of a polymer/drug mixture which may be place on one stent end such that the middle is free of any polymer/drug (column 6 lines 41-45). The coating may include an RGD peptide containing compound, a plurality of drugs, and plurality of polymers which is interpreted by examiner to meet the limitations of a plurality of different layers.

The outer ends are inherently more "loose" and flexible than the middle portion due to the end portions only being connected on the "middle" side.

Scott is silent as to directly adhering the sleeve coating material to the metal surface of the stent. Myers teach stents with sleeve coatings wherein the material may be affixed to the stent by thermoplastic adhesive and the coatings remained intact after collapsing and enlarging the stent (see abstract and examples). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify

the stent in Scott to include adhesion points, as taught in Myers, to secure the sleeve position and prevent migration of the sleeve from the stent.

Claims 1,91-101,105-123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al. USPN 5464650 ("Berg") in view of Scott et al. 5383928 ("Scott"), Nolting et al. USPN 6488701 ("Nolting"), and Jang USPUB 2004/0106985 ("Jang").

Berg disclose stainless steel, balloon expandable (claims 100-101,119-120) stents comprising a coating of a polymer and drug, wherein the coating is applied in a plurality of layers of the same coating material (claims 92,93,111-112,114-115). The coating adheres to the stent struts, and expands with the stent, so is thus considered a bioadhesive, gel-like, and having apertures/perforations as broadly claimed (claims 91,95,96,110). The free ends of the stent are inherently more flexible than the middle portion due to the end portions only being connected on the "middle" side (claims 98-99,117-118).

Regarding claims 1, 108, and 109, Berg is silent as to providing the coating on an end portion and not on a middle portion of the stent. Each of Scott and Nolting teach coated stents for delivering drug to the blood vessel wherein the drug delivery coating is placed only on an end portion of the stent in order to provide a targeted delivery. See Nolting col. 7:50-57 and Scott col. 5:26-33 and c6:41-45. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the drug

delivery stent of Berg to include the coating at only one or both end portions, as taught by Scott and Nolting, in order to provide a targeted delivery of therapeutic agents.

Regarding claim 94 and 113, Berg is silent as to providing a plurality of coating layers having different coating materials. Scott teach at lines 4-5 of col. 6 that plurality of layers may comprise different materials in order to achieve a desired release profile. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the drug delivery stent of Berg to include a plurality of layers having different materials, as taught by Scott, in order to achieve a desired release profile.

Regarding claims 97,105-107,116, and 121-123, Berg is silent as to specifically using drugs such as RGD peptide containing compounds, tranilast, trapidil, or probucol. Berg do disclose the drug used may be one of a plethora of drug classes at col. 2 lines 55-62. Jang teaches at paragraphs [0344-0346] an expandable stent comprising therapeutic compounds which may include anti proliferative agents, inhibitors of vasoactive mechanisms inflammatory actions, or RGD peptide containing compounds in order to promote endothelialization. Tranilast, Trapidil, and Probucol are known therapeutic inhibitors or anti-proliferative agents in the art. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the stent disclosed by Berg, and modified by Nolting or Scott, to include RGD peptide containing compounds, Tranilast, Tropidil, or Probucol, as taught by Jang '985, in order to promote endothelialization.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/
Primary Examiner
Art Unit 3774